

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

NORRIS COCHRAN, in his official
capacity as Acting Secretary of Health and
Human Services,

DANIEL J. BARRY, in his official
capacity as Acting General Counsel of the
United States Department of Health and
Human Services,

HEALTH RESOURCES AND
SERVICES ADMINISTRATION,

DIANA ESPOSITO, in her official
capacity as Acting Administrative of the
Health Resources and Services
Administration,

Defendants.

Civil Action No. 3:21-cv-634

MOTION OF NOVO NORDISK
INC. AND NOVO NORDISK
PHARMA, INC. FOR LEAVE TO
FILE *AMICUS CURIAE* BRIEF IN
SUPPORT OF PLAINTIFF'S
MOTION FOR PRELIMINARY
INJUNCTION

**UNOPPOSED MOTION OF
NOVO NORDISK INC. AND NOVO NORDISK PHARMA, INC.
FOR LEAVE TO FILE AN *AMICUS CURIAE* BRIEF IN SUPPORT OF
PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION**

Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (together, “Novo”) respectfully request leave to file the attached *amicus curiae* brief in support of the motion for a preliminary injunction filed by plaintiff Sanofi-Aventis U.S., LLC. A “classic role of an *amicus curiae* is to assist in a case of general public interest,” and that is precisely what Novo aims to do here. *United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002) (internal quotation marks omitted). This motion is unopposed. Counsel for the government and counsel for Sanofi have both consented to this filing.

Sanofi’s motion for a preliminary injunction seeks to prevent the U.S. Department of Health & Human Services (“HHS”) from forcing manufacturers to participate in a constitutionally invalid administrative dispute-resolution process that is being used to enforce a December 30, 2020 decision by HHS that exceeds the agency’s lawful authority by requiring manufacturers to transfer their drugs at deeply discounted prices to large commercial pharmacies. *See 340B Drug Pricing Program: Administrative Dispute Resolution Regulation*, 85 Fed. Reg. 80,632 (Dec. 14, 2020) (codified at 42 C.F.R. pt. 10) (the “ADR rule”); HHS, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020) (the “December 30, 2020 decision”). Novo’s interest in Sanofi’s motion is substantial because Novo is the plaintiff in a case that is pending before this Court that raises similar issues. *See Novo Nordisk Inc v. Dept. of Health & Human Servs.*, No. 3:21-

cv-00806 (D.N.J.) (filed Jan. 15, 2021). In that case, Novo is also challenging HHS's December 30, 2020 decision, arguing that the decision is arbitrary and capricious and contrary to law. The obligations that HHS seeks to impose go far beyond what the statute authorizes or requires.

Unlike Sanofi, Novo has not yet filed its own motion for a preliminary injunction because no covered entities have initiated dispute-resolution proceedings against Novo seeking to enforce HHS's December 30, 2020 decision. Nonetheless, the Court's resolution of the issues raised in Sanofi's motion are likely to have a direct impact on Novo's interests and the resolution of the issues raised in its case. As a result, Novo seeks leave to file an amicus brief to express its views on the important constitutional and administrative law issues raised by HHS's unlawful regulatory actions, which are relevant to both this case and Novo's case.

As explained in more detail in the attached brief, HHS's failure to police widespread abuses of the 340B program has enabled large commercial pharmacies to syphon off \$3.3 billion a year in profits at the expense of drug manufacturers and vulnerable patients. If HHS's actions are not struck down by this Court, and if HHS is able to avoid meaningful judicial review by forcing manufacturers to participate in an unconstitutional process established by the ADR rule, Novo and other manufacturers face substantial, irreparable harm.

Novo's brief in support of Sanofi's request for preliminary relief is to the point and seeks to provide the Court with a "helpful analysis of the law." *Bryant v. N.J. Dep't of Transp.*, 987 F. Supp. 343, 346 n. 3 (D.N.J. 1998) (citation omitted). It brings a unique perspective to this case that is likely to be helpful to the Court because it draws on materials and arguments that are not addressed in detail in Sanofi's submission. This Court has "broad discretion" to permit Novo to participate as an *amicus curiae*. *See id.* (citing cases); *see also Neonatology Assocs., P.A. v. Commissioner*, 293 F.3d 128, 132 (3d Cir. 2002) (explaining why it is "preferable to err on the side of granting leave" to file an *amicus* brief). Novo requests that the Court exercise that discretion here.

WHEREFORE, Novo respectfully requests that the Court grant this motion for leave to file an *amicus curiae* brief and accept the accompanying proposed brief for filing.

Dated: February 25, 2021

Respectfully submitted,

/s/ Israel Dahan

Israel Dahan (NJ Bar No. 042701997)

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